U.S. Food and Drug Administration

Frequently Asked Questions: Tobacco Products Scientific Advisory Committee's Report and Recommendations on the Impact of the Use of Menthol in Cigarettes

Throughout this document FDA uses the following terms:

- ***The Committee – refers to the Tobacco Products Scientific Advisory Committee***
- ***Menthol Report or the Report – refers to the TPSAC report and recommendations on the impact of the use of menthol in cigarettes on the public health required by the Family Smoking Prevention and Tobacco Control Act***
- ***The Secretary – refers to the Secretary of Health and Human Services***
- ***The Agency – refers to the U.S. Food and Drug Administration***

Why was the Committee charged with developing and submitting a report and recommendations to the Secretary on the impact of the use of menthol in cigarettes on the public health?

Section 907 (e) of the Tobacco Control Act requires the Tobacco Products Scientific Advisory Committee (TPSAC) to submit a report and recommendations to the Secretary of Health and Human Services (HHS) on the impact of the use of menthol in cigarettes on the public health – including use among children, African Americans, Hispanics, and other racial/ethnic minorities – no later than one year after its establishment. The report and recommendations are due to the Secretary by March 23, 2011. The report is considered submitted to the Secretary once received by the U.S. Food and Drug Administration (FDA).

Why wasn't menthol included in the original flavor ban?

The Tobacco Control Act banned cigarettes containing certain characterizing fruit, candy, or clove flavors as of September 22, 2009. While the statute did not include menthol-flavored cigarettes in the prohibition of certain characterizing flavors, Congress has specifically asked TPSAC to provide a report and recommendation on the public health impact of the use of menthol in cigarettes, including its use among children, African-Americans, Hispanics, and other minority communities. The topic of the public health impact of the use of menthol in cigarettes was the first topic referred to the TPSAC.

What main questions does the report and recommendations on the impact of the use of menthol in cigarettes address?

The TPSAC chose to address and answer the following questions in its report:

Related to Individual Smokers

- Does availability of menthol cigarettes increase the likelihood of experimentation?
- Does availability of menthol cigarettes increase the likelihood of becoming a regular smoker?
- Does inclusion of menthol in cigarettes increase the likelihood of the smoker becoming addicted?
- Does inclusion of menthol in cigarettes increase the degree of addiction of the smoker?
- Are smokers of menthol cigarettes less likely to quit successfully than smokers of non-menthol cigarettes?
- Do biomarker studies indicate that smokers of menthol cigarettes receive greater doses of harmful agents per cigarette smoked compared with smokers of non-menthol cigarettes?
- Do smokers of menthol cigarettes have increased risk for diseases caused by smoking compared with smokers of non-menthol cigarettes?

Smoking at the Population Level

- Does the availability of menthol cigarettes increase the prevalence of smoking in the population, beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?
- Does tobacco company marketing of menthol cigarettes increase the prevalence of smoking beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?

What will the FDA do with the report and recommendations on the public health impact of the use of menthol in cigarettes? When will FDA act on the recommendations provided by the TPSAC in the report?

TPSAC's menthol report will undergo a thorough review by experts within the FDA Center for Tobacco Products. The FDA will consider the report and recommendations of the Committee, the industry perspective document, and continue to review all of the available science concerning menthol cigarettes. The FDA will then make a determination about what future action(s), if any, are warranted.

The Tobacco Control Act does not set a required deadline or timeline for the FDA to act on the recommendations provided by the Committee in the report.

The FDA recognizes the strong interest in this issue among all stakeholders and will continue to communicate the steps the FDA is taking as it determines what future regulatory actions, if any, are warranted. FDA intends to provide its first progress report on the review of the science in approximately 90 days from the report due date.

Any future action(s) taken by the FDA to regulate the sale or distribution of menthol cigarettes or establish a tobacco product standard for menthol cigarettes will require rule making that includes public notice and the opportunity for public comment.

Who wrote the report and recommendations on the impact of the use of menthol in cigarettes?

The draft report was written by TPSAC members working in writing workgroups of the TPSAC Menthol Report Subcommittee. Drafts of the report were presented to TPSAC where they were discussed and deliberated on by the full Committee. The report was finalized after discussion and deliberation by the TPSAC and the report and recommendations were submitted to FDA by TPSAC. The committee recommendations were developed by the full Committee.

- The most recent roster of the Menthol Report Subcommittee is available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM242957.pdf.

- The roster of the TPSAC (including voting and non-voting members) is available at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180906.htm.

What information was used by the Committee to develop the report and recommendations on the impact of the use of menthol in cigarettes?

TPSAC reviewed and considered multiple sources of evidence for the report and recommendations on the impact of the use of menthol in cigarettes. Sources of evidence that were reviewed and considered included peer-reviewed literature, additional data and information commissioned by the FDA at the request of the TPSAC, tobacco company submissions, and public comments from a wide range of stakeholders. Examples of sources of evidence that were reviewed and considered include available industry documents from the Legacy Tobacco Documents Library, and industry presentations on menthol in cigarettes as it relates to characterization of menthol, clinical effects of menthol, biomarkers of disease risk, marketing data, and population effects.

Were industry representatives allowed to participate in the development of the Menthol Report?

Yes. While tobacco industry representatives did not participate in the writing workgroups of the Menthol Report Subcommittee (because, as non-voting members who are not Special Government Employees, they are not permitted access to trade secret or commercial confidential information that was disclosed to members of the writing workgroups) the industry representatives had many opportunities to contribute to the development of the report, including:

- Participating in open discussions and deliberation on how the report should be organized
- Participating in open discussions and deliberation on the non-confidential/trade secret evidence that the TPSAC relied on in the report
- Participating in open discussions and deliberation on the draft report chapters

- Participating in discussions regarding the development of the Committee recommendations included in the final report
- Participating in open discussions and deliberation regarding the final report

In addition, FDA asked the industry representatives to develop an industry perspective document that, like the TPSAC Menthol Report, would address the public health impact of the use of menthol in cigarettes. Once received, this document will be available to the public on the FDA Center for Tobacco Products' web site at www.fda.gov/tobaccoproducts.

How are TPSAC members screened for conflict of interest?

At the time of appointment, the agency conducted a careful conflict of interest screening process for all TPSAC members who are Special Government Employees (SGE) and Regular Government Employees (RGE). Each SGE and RGE was found to satisfy the conflict of interest provision of the Tobacco Control Act, as well as federal ethics and conflict of interest laws including, but not limited to, those found at 18 U.S.C. Section 208 and Section 712 of the Federal Food, Drug, and Cosmetic Act. In accordance with federal statutes, regulations, and FDA procedures, FDA screened for conflict of interest before every meeting, and will continue to screen committee members for potential conflicts of interest arising from particular matters to be considered by the TPSAC.

The roster of the TPSAC and their curriculum vitae are available at: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180906.htm.